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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,721	02/18/2004	Jerry Jonn	118560	1723

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EXAMINER	
NEAL, TIMOTHY J	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/779,721	JONN ET AL.	
	Examiner	Art Unit	
	Timothy J. Neal	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *see next page*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Information Disclosure Statement dates:

6/09/2004
9/12/2005
2/14/2006
2/28/2006
4/28/2006

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DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-23, 25, 34-39, and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US 5,259,835) in view of Ballance et al. (US 6,439,789).

Clark discloses:

Claim 1: a flexible material (Fig 1 Item 30 and Fig 10 Item 30 and Fig 6); an adhesive substance applied over at least a portion of a bottom side of said flexible material (Col 4 Line 32); and an adhesive composition permeated throughout at least a portion of said flexible material (Col 4 Line 14).

Claim 2: said flexible material is a mesh (Col 3 Line 54).

Claim 3: said flexible material comprises perforations or tear lines (Fig 6 Item 52).

Claim 4: said flexible material is flexible and porous (Col 3 Line 35 and Col 3 Line 54).

Claim 5: said flexible material is substantially free of elastin (not stated in disclosure as being present or required for this device).

Claim 6: said flexible material is elastic (Col 3 Line 34).

Claim 7: said adhesive substance is applied over a first and a second portion of said flexible material (Fig 6 Item 40).

Claim 8: said first and second portions are located substantially at opposite ends of said flexible material (Fig 6 Item 40).

Claim 9: said first and second portions do not cover an entire surface area of said flexible material (Fig 6 Item 40).

Claim 10: said flexible material comprises perforations or tear lines proximate to said first and second portions (Fig 6 Item 52).

Claim 11: said adhesive substance is a pressure sensitive adhesive (Col 4 Line 45, stated as well known in the art by the reference and by the Applicant (paragraph 49 of Specification).

Claim 12: said pressure sensitive adhesive has a weaker bonding strength than said adhesive composition (Col 4 Line 33).

Claim 13: said adhesive substance does not interact with said adhesive composition (Fig 10).

Claim 18: said adhesive composition substantially covers surfaces on at least said bottom side and a top side of said flexible material (Fig 10).

Claim 19: said adhesive composition substantially does not cover said adhesive substance (Fig 10).

Claim 25: the flexible material is not biodegradable (Col 3 Line 40; polyolefins are considered generally to be non-biodegradable).

Claim 30: said adhesive substance is applied over substantially the entire bottom side of said flexible material (Fig 2 Item 40).

Claim 31: said adhesive substance is permeated by said adhesive composition (Col 4 Line 38).

Claim 32: said flexible substrate (does) not include features that penetrate an underlying substrate during use (Fig 8 Item 56). A barrier layer to prevent the flow of adhesive into the wound is described. The barrier layer may be used with any of the embodiments, therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify any of Clark's embodiments to include the barrier layer. Such a modification would prevent the adhesive from flowing into the wound.

Claim 33: one or more adhesive strips attached to the flexible material, wherein the adhesive substance is provided on the one or more adhesive strips (Fig 2 Item 40).

Claim 34: a method of bonding tissue, comprising: placing a flexible substrate over a section of tissue, wherein said flexible substrate comprises a flexible material and an adhesive substance applied over at least a portion of a bottom side of said flexible material (Col 4 Line 14); applying an adhesive composition over and substantially covering at least a portion of the flexible substrate (Col 4 Line 14); and allowing the adhesive composition to permeate into and under the flexible substrate and polymerize to form a composite structure bonded to said tissue (Figs 10 and 19).

Claim 35: said section of tissue includes a wound to be closed (Figs 10 and 19).

Claim 36: said placing comprises: fixing a first portion of said flexible substrate to said section of tissue on a first side of said wound; approximating edges of said wound; and fixing a second portion of said flexible substrate to said section of tissue on a second of said wound opposite said first side of said wound (Figs 10 and 19).

Claim 37: removing said first and second portions of said flexible substrate (Figs 10 and 19).

Claim 38: a third portion of said flexible substrate remains, covering said wound (Figs 10 and 19).

Claim 39: said removing comprises trimming said first and second portions of said flexible substrate (Col 8 Line 23).

Claim 41: said applying comprises: placing a quantity of said adhesive composition on an exposed side of the flexible substrate; and spreading the quantity of adhesive composition to substantially cover the flexible substrate (Fig 19 and Col 3 Line 50).

Claim 42: said section of tissue has a length and a width, said length being longer than said width; said wound has a length and a width, said length being longer than said width; and said wound extends lengthwise in a lengthwise direction of said section of tissue (Fig 19).

Claim 43: the flexible material is sterilized (Col 9 Line 30).

Claim 44: the adhesive composition is sterilized (Col 9 Line 43).

Regarding claims 1-44, specifically claims 1, 14-17, 20-29, and 40, Clark does not disclose the adhesive being polymerizable, a polymerization initiator or rate modifier for said polymerizable adhesive composition disposed in or on said flexible material; said polymerization initiator or rate modifier is immobilized on said flexible material; a bioactive material disposed in or on said flexible material; said bioactive material is not immobilized on said flexible material, but is soluble or dispersible in said polymerizable adhesive composition; the flexible material is biodegradable; the flexible material is not biodegradable; the flexible material and the polymerizable adhesive composition are together biodegradable; the flexible material and the polymerizable adhesive composition are together not biodegradable; the article is opaque; the article is translucent; said placing comprises: fixing a first lengthwise end of said flexible substrate to said section of tissue on a first lengthwise end of said wound; approximating edges of said wound; and fixing a second lengthwise end of said flexible substrate to said section of tissue on a second lengthwise end of said wound opposite said first lengthwise end of said wound.

Regarding claims 1-23, 25, 34-39, and 41-44, Ballance teaches a 1,1-disubstituted monomer and a cyanoacrylate monomer that are both polymerizable (Col 6 Lines 35-53). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Clark's adhesive to include Ballance's polymerizable adhesive. Such a modification would provide protective coverage of wounds with a fast-acting surgical adhesive.

Ballance also teaches the use of a polymerization initiator and bioactive material (Col 6 Lines 55-65). Ballance also teaches the initiator being immobilized (Fig 1 Item 120) and the bioactive material being dispersible in the polymerizable composition (Col 7 Line 20). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Clark's article to include Ballance's polymerizable initiator and bioactive material. Such a modification would accelerate polymerization and the use of bioactive agents can help the healing process. By keeping the initiator immobilized, the polymerizable adhesive will avoid polymerizing until the desired time, for example, not until after the bandage is in place. The bioactive material being dispersible in the polymerizable composition allows it to reach the wound so that it can be effective.

Claims 24, 26, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US 5,259,835) and Ballance et al. (US 6,439,789) in view of Porzilli (US 5,336,209).

Clark and Ballance disclose the invention substantially as claimed as stated above and do not disclose the specific limitations as stated above.

Regarding **claims 24, 26, 28, and 29**, Porzilli teaches an opaque or translucent bandage that is biodegradable (Claims 5, 13, and 14 and Col 2 Line 35). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Clark and Ballance's article to include Porzilli's translucent or opaque biodegradable characteristics. Such a modification would either

prevent the wound from being seen or allow limited visualization of the wound. A biodegradable substance will degrade overtime and not need to be removed. Cyanoacrylate is a biodegradable adhesive, so the combination of Porzilli's biodegradable bandage with the cyanoacrylate adhesive as discussed above would satisfy the limitations of claim 26. Also, the Examiner notes that the Applicant has admitted that biodegradable and non-biodegradable adhesives are known in the art (Paragraph 33 of Specification), so upon argument that cyanoacrylate is not biodegradable, the rejection will stand that it would have been obvious to a person having ordinary skill in the art to combine Porzilli's biodegradable material with one of the known biodegradable adhesives so that the article will not need to be removed and is environmentally friendly.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US 5,259,835) and Ballance et al. (US 6,439,789).

Clark and Ballance disclose the invention substantially as claimed as stated above and do not disclose the specific limitations as stated above.

Regarding **claim 27**, the Applicant has admitted that biodegradable and non-biodegradable adhesives are known in the art (Paragraph 33 of Specification). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Clark and Ballance's article to include a non-biodegradable polymerizable adhesive composition. Such a modification would require the bandage to be removed from the wound. This would allow the user to keep the

article on the wound until the wound is completely healed. A biodegradable composition may biodegrade prior to complete healing.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US 5,259,835) and Ballance et al. (US 6,439,789) in view of Vandruff (US 2002/0193721).

Clark and Ballance disclose the invention substantially as claimed as stated above and do not disclose the specific limitations as stated above.

Vandruff teaches said placing comprises: fixing a first lengthwise end of said flexible substrate to said section of tissue on a first lengthwise end of said wound; approximating edges of said wound; and fixing a second lengthwise end of said flexible substrate to said section of tissue on a second lengthwise end of said wound opposite said first lengthwise end of said wound (Figs 9 and 10). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the method of Clark and Ballance to include Vandruff's placing step. Such a modification would cover a wound in the lengthwise direction with a single article.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SUPERVISORY PATENT EXAMINER
8/4/06